REMARKS

I. Introduction

This paper is submitted in response to the Advisory Action mailed June 6, 2005 for the above-identified patent application. A two (2) month extension to the time for responding to the Advisory Action is respectfully requested. Claims 1-32 are pending in the application. Claims 6-13 and 19-32 have been withdrawn from consideration. Claim 15 has previously been canceled. Claims 1-5, 14 and 16-18 have been rejected.

Claims 1, 2 and 14 are currently amended. New claims 33 and 34 have been added. Applicants submit that the amendments and new claims are fully supported in the Specification and the drawings, as originally filed, and therefore no new matter has been introduced. Accordingly, claims 1-5, 14, 16-18, 33 and 34 are pending in the present application and are respectfully submitted for reconsideration.

II. The Rejections Under 35 U.S.C. §102 Should Be Withdrawn

Claims 1, 2, 4, 5, 14 and 15 have been rejected under 35 U.S.C. § 102(a) as being unpatentable in view of International Publication No. WO 98/35985 A1 to Hanash ("Hanash"). The Examiner alleges that the prior art teaches an antibody that binds to the heterodimer of S100-A9 and S100-A8. In addition, the Examiner states that the prior art teaches that the presence of the S100 protein is indicative of lung cancer in a subject.

Applicants have amended independent claims 1 and 14 to recite diagnosis of cancer in a subject comprising detecting S100-A7 protein. In contrast, Hanash does not disclose the detection of S100-A7 protein for the diagnosis of cancer, as recited in

amended independent claims 1 and 14. Thus, Hanash does not disclose each and every element of the claim in exactly the same way, as required under 35 U.S.C. § 102. As claims 2, 4 and 5 depend from independent claim 1, these dependent claims are patentable for at least the same reasons. Consequently, reconsideration and withdrawal of the rejection of claims 1, 2, 4, 5 and 14 under 35 U.S.C. § 102(a) is respectfully requested.

Applicants have also added new claims 33 and 34 directed to the diagnosis of cancer in which S100-A7 or S100-A8 protein is an indicator of a subject with breast cancer or colon cancer. In contrast, Hanash discloses protein markers for lung cancer. Thus, Hanash also does not disclose each and every element of the claims 33 and 34, as required under 35 U.S.C. § 102. Moreover, the antibody disclosed in Hanash binds an epitope formed by heterodimerization to determine the amount of S100-A9 in a subject having lung cancer. Because of the specificity of the antibody disclosed by Hanash, one skilled in the art would not expect that elevated levels of S100-A8 or S100-A7 can be detected in the serum of patients with breast cancer or colon cancer. Thus, Applicants respectfully submit that new claims 33 and 34 are patentable and in a condition for allowance.

Claims 14 and 15 have been rejected under 35 U.S.C. § 102(a) as being unpatentable in view of Newton *et al.* J. IMMUNOL. 160:1427-35 (1998) ("Newton"). Claim 15 has previously been canceled and, therefore, the rejection with regard to this claim is now moot.

As stated above, Applicants have amended independent claim 14 to recite diagnosis of cancer in a subject comprising detecting S100-A7 protein. Newton does not disclose the diagnosis of cancer by detection of S100-A7 protein, as recited in amended independent claim 14. Moreover, Newton does not disclose the diagnosis of cancer in which S100-A7 or S100-A8 protein is an indicator of a subject with breast cancer or colon cancer, as recited in new claims 33 and 34. Thus, Newton does not disclose each and every element of the pending claims in exactly the same way, as required under 35 U.S.C. § 102. Therefore, reconsideration and withdrawal of the rejection of claim 14 under 35 U.S.C. § 102(a) and allowance of all the pending claims is respectfully requested.

III. The Rejections Under 35 U.S.C. §103 Should Be Withdrawn

Claims 3 and 16-18 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Hanash further in view of BIO-RAD. The Examiner alleges that the prior art teaches an antibody that binds to the heterodimer of S100-A9 and S100-A8. In addition, the Examiner states that the prior art teaches that the presence of the S100 protein is indicative of lung cancer in a subject.

To establish obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981 (CCPA 1974). Applicants have amended independent claims 1 and 14 to recite diagnosis of cancer in a subject comprising detecting S100-A7 protein. As stated above, Hanash fails to teach or suggest all the recitations of independent claims 1, 14, 33 and 34. In particular, there is no disclosure of an antibody that may be used to determine an elevation of

S100-A7 protein in the serum of a subject having cancer. Moreover, there is no disclosure of an antibody that may be used to determine an elevation in either S100-A8 or S100-A7 in the serum of a subject having breast cancer or colon cancer. BIO-RAD does not teach or suggest the missing recitations of the currently pending independent claims. As claims 3 and 16-18 depend from independent claims 1 and 14, these dependent claims are patentable for at least the same reasons. Therefore, reconsideration and withdrawal of the rejection of claims 3 and 16-18 as obvious in view of Hanash further in view of BIO-RAD and allowance of all the pending claims is respectfully requested.

IV. Double Patenting Rejections

Claims 1, 2, 4 and 5 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-15 of copending Application No. 10/461,424. In addition, claims 3 and 14-18 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-15 of copending Application No. 10/461,424 further in view of BIO-RAD.

Applicants will file a terminal disclaimer, in compliance with 37 C.F.R. 1.321(c), to overcome the rejection based on the judicially created doctrine of double patenting upon notification of allowable claims.

V. Conclusion

In view of the foregoing, reconsideration and allowance of pending claims 1-5, 14, 16-18, 33 and 34 is respectfully requested.

A two (2) month extension to the time for responding to the Official Action is respectfully requested. Payment of the extension fee is to be made according to the Credit Card Payment Form attached herewith. Applicants believe that no additional fees are required in connection with this response. However, if additional fees are required, the Commissioner is hereby authorized to charge any additional payment, or credit any overpayment, to Deposit Account No. 01-2300 **referencing Attorney Docket Number 108140.00014.**

If for any reason the Examiner determines that the application is not now in condition for allowance or believes that an interview would expedite consideration of this application, it is respectfully requested that the Examiner contact the Applicant's undersigned counsel at the telephone number, indicated below, to discuss any outstanding issues in order to expedite the disposition of this application.

Respectfully submitted,

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Appl. No. 09/848,948
Reply to Advisory Action mailed June 6, 2005
Response dated July 8, 2005

FEE CALCULATION

Any additional fee required has been calculated as follows:

____ If checked, "Small Entity" status is claimed.

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT	(Column 2) HIGHEST NO. PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE	SMALL ENTITY ADD'L FEE	OR	LARGE ENTITY RATE	LARGE ENTITY ADD'L FEE
TOTAL CLAIMS	31 MINUS	32	= -0-	x $25	$-0-		x $50	$-0-
INDEP CLAIMS	6 MINUS	6	= -0-	x $100	$-0-		x $200	$-0-
☐ FIRST PRESENTATION OF MULTIPLE DEP. CLAIM				+ $180	$-0-	OR	+ $360	$-0-
					$-0-			$-0-

The U.S. Patent and Trademark Office is hereby authorized to charge and deficiency or credit any overpayment of fees associated with this communication to Deposit Account No. **01-2300** referencing docket number **108140.00014**.